

REMARKS/ARGUMENTS

Applicant acknowledges receipt of the Office Action dated March 2, 2011. By this Response, claim 24 is amended. Claims 13-15, 17, 19-21, 24, 25, 27-29, and 31 are now pending in the application. The Examiner rejected claims 13-15, 17, 19-21, 24, 25, 27-29, and 31 under 35 U.S.C. §103 as being unpatentable over Cooper et al., U.S. Patent No. 5,211,832 (“*Cooper*”) in view of Pickford et al., WO 03/089023 (“*Pickford*”) or Ogle, U.S. Patent No. 6,267,782 (“*Ogle*”). In addition, claims 13-15, 17, 19-21, 24, 25, 27, 28, and 31 are rejected under 35 U.S.C. §103 as being unpatentable over Minevski et al., U.S. Patent Application Publication No. 2004/0121290 (“*Minevski*”) in view of *Pickford* or *Ogle*. The Examiner also rejected claim 29 under 35 U.S.C. §103 as being unpatentable over *Minevski* in view of *Pickford* or *Ogle* and further in view of Rosenberg et al., U.S. Patent No. 5,185,075 (“*Rosenberg*”). Moreover, the Examiner rejected claims 13-15, 17, 19-21, 24, 25, 27-29, and 31 under 35 U.S.C. §112 as failing to comply with the enablement requirement. Claims 24, 25, 27-29, and 31 are also provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-11 of co-pending application serial no. 12/539,028 (“*the ‘028 application*”) in view of *Cooper* or *Minevski*. Applicant believes the pending claims are allowable over the art of record and respectfully requests reconsideration and allowance of all claims.

I. Claims 13-15, 17, 19-21, 24, 25, 27-29, and 31 are patentable over *Cooper* in view of *Pickford* or *Ogle*.

Applicant respectfully traverses the Examiner's rejection of claims 13-15, 17, 19-21, 24, 25, 27-29, and 31 under §103 as being unpatentable over *Cooper* in view of *Pickford* or *Ogle*. Applicant submits that the cited references do not provide a *prima facie* case of obviousness for rejecting such claims.

Claim 13 is an independent claim upon which claims 14, 15, 17, 19-21, and 31 depend. Claim 24 is an independent claim upon which claims 25 and 27-29 depend.

The Examiner has pointed out that in *Cooper's* Examples 6, 7 and 8 a titanium workpiece was anodised in a phosphoric acid solution at an applied voltage of 75 V or 100 V for a period of

time greater than 30 minutes. The Examiner states that these are "the same anodizing conditions" disclosed and claimed by the Applicant, and because the process steps are the same, the characteristics of the anodised layer of *Cooper* would have been expected to be the same as those of Applicant's layer as recited in the claims.

As noted in Applicants' response of January 12, 2011, "the sensitivity of certain characteristics of the materials produced using the process of *Cooper* (e.g., zero current voltage) to subtle changes in the anodising solution (e.g., a 9 percent increase in the total water content of the phosphoric acid component, which constitutes only one part combined with nine parts aprotic solvent) is inconsistent with an expectation that the product and process taught by *Cooper* teaches or suggests the recitations of claims 13 and 24." The attached declaration of Dr. Andrew Turner is consistent with Applicants' position and contrary to the Examiner's position that *Cooper* teaches "the same anodizing conditions" and would create the same anodised layer of claims 13 and 24. More specifically, Dr. Turner's experiments clearly demonstrate the anodised surface of *Cooper* lacks at least "pits being of a diameter about 5 microns and occupying between 15 and 20% of the surface area of the surface layer." This is particularly clear from a comparison between the SEM images of a sample treated by *Cooper's* process (figure 6), and the SEM images of samples treated by a process of the present invention (figures 7 and 8).

As previously noted by the Examiner in the Office Action dated April 30, 2010, "claim 13 differs from the description of the product of *Pickford* by reciting the surface layer is an anodized hard layer *including pits.*" (pg. 3, lns. 10-11, emphasis added). Because neither *Cooper* nor *Pickford* alone teaches the recited "pits," there can be no reason or motivation for one of ordinary skill in the art to combine these references to teach the implant and method of claims 13 and 24, respectively. Indeed, one of ordinary skill in the art would have neither success nor an expectation of the same in such a combination.

Claims 13 and 24 further require "ions of a biocidal metal" included in the pits by ion exchange. *Ogle* teaches the incorporation of an antimicrobial metal into medical articles by electroplating (column 2, line 66) or incorporating metal leaf or silver wire (column 3, lines 12-14). However, *Ogle* relies on reduction (chemically or electrochemically) of a metal composition, resulting "in the deposition of antimicrobial metal." Incorporating silver in ionic form, much less by ion exchange, into an anodised surface is clearly not suggested.

Because *Cooper* does not provide an anodised surface having the features required by the recitations of claims 13 and 24 and *Ogle* does not suggest incorporating an antimicrobial metal in ionic form by ion exchange, the combination of their teachings also does not lead to the requirements of claims 13 and 24.

In view of the recitations in independent claims 13 and 24 that are neither taught nor suggested by *Cooper* in view of *Pickford* or *Ogle*, Applicant respectfully submits that independent claims 13 and 24 are allowable over *Cooper* in view of *Pickford* or *Ogle*. Consequently, Applicant requests that the Examiner withdraw the §103 rejections of dependent claims 14, 15, 17, 19-21, 25, 27-29, and 31, since it is submitted that independent claims 13 and 24 are allowable. Dependent claims 14, 15, 17, 19-21, 25, 27-29, and 31 must be allowable, since they carry all the limitations of the allowable independent claims 13 and 24 to which they refer.

II. Claims 13-15, 17, 19-21, 24, 25, 27, 28, and 31 are patentable over *Minevski* in view of *Pickford* or *Ogle*.

Applicant respectfully traverses the Examiner's rejection of claims 13-15, 17, 19-21, 24, 25, 27, 28, and 31 under §103 as being unpatentable over *Minevski* in view of *Pickford* or *Ogle*. Applicant submits that the cited references do not provide a *prima facie* case of obviousness for rejecting such claims.

Claim 13 is an independent claim upon which claims 14, 15, 17, 19-21, and 31 depend. Claim 24 is an independent claim upon which claims 25, 27, and 28 depend.

In Examples 1-3 of *Minevski*, the anodising voltage was applied for 3 minutes, at voltages of 50 V, 75 V and 25 V, providing gold colour, purple colour and blue colour, respectively. Example 4 used 50 V for 30 minutes, providing the same gold colour as did Example 1 (i.e., 50 V for 3 minutes). Example 5 relates to a variety of anodising processes that are followed by coating with hydroxyapatite by plasma spraying. In the first four tests, anodising was performed for 3 minutes (at voltages between 25 V and 100 V), while in all the remaining tests anodizing was performed at 25 V for 1 minute, 3 minutes, 10 minutes or 30 minutes.

It will thus be appreciated that *Minevski* describes 16 different anodising processes, on different substrates and changing various parameters, but in no case was a voltage "above 50 V" applied for a period "of more than 30 minutes." Although Example 4 applied 50 volts for 30 minutes, no difference as compared to anodising for only 3 minutes was suggested as it provided "the same strong gold colour as the coupon in Example 1." Therefore, *Minevski* does not teach or suggest that there would be any benefit in applying a voltage "above 50 volts" for a period "of more than 30 minutes," as in almost every case the anodising was completed in 3 minutes, and in the one case when the treatment was continued for 30 minutes there was no observed difference in the result.

Minevski is not intending to produce a surface oxide with ion exchange properties or including pits; rather, as explained in paragraph 44, "[t]he surface treatment of the present invention provides excellent corrosion protection of metal implants and minimises toxicological effects", which implies the absence of any pits. There is therefore no teaching by *Minevski* that would suggest any reason to subject *Minevski*'s anodised surface to a subsequent ion exchange process to include ions of biocidal metal material.

The Examiner has suggested combining the teaching of *Minevski* with the teaching of *Pickford*. However, as previously noted by the Examiner in the Office Action dated April 30, 2010, "claim 13 differs from the description of the product of *Pickford* by reciting the surface layer is an anodized hard layer *including pits*." (pg. 3, lns. 10-11, emphasis added) In the October 13, 2010 Office Action, the Examiner acknowledges that "claim 24 differs from the process of *Pickford* by reciting anodizing at a voltage *above 50 V*." (pg. 6, lns. 2-3, emphasis added). Neither *Pickford* nor *Minevski* suggests the formation of a hard oxide layer with pits of "diameter about 5 microns and said pits occupying between 15 and 20% of the surface area of the surface layer, said pits extending through said hard layer into said metal substrate." As such, *Pickford* cannot remedy the deficiencies of *Minevski* to render obvious the recitations of claims 13 and 24.

The Examiner has alternatively suggested combining the teaching of *Minevski* with the teaching of *Ogle*. However, as detailed above, *Ogle* does not teach "ions of a biocidal metal" included in the pits by ion exchange as required by claims 13 and 24.

In view of the recitations in independent claims 13 and 24 that are neither taught nor suggested by *Minevski* in view of *Pickford* or *Ogle*, Applicant respectfully submits that independent claims 13 and 24 are allowable over *Minevski* in view of *Pickford* or *Ogle*. Consequently, Applicant requests that the Examiner withdraw the §103 rejections of dependent claims 14, 15, 17, 19-21, 25, 27, 28, and 31, since it is submitted that independent claims 13 and 24 are allowable. Dependent claims 14, 15, 17, 19-21, 25, 27, 28, and 31 must be allowable, since they carry all the limitations of the allowable independent claims 13 and 24 to which they refer.

III. Claim 29 is patentable over *Minevski* in view of *Pickford* or *Ogle* and further in view of *Rosenberg*.

Applicant respectfully traverses the Examiner's rejection of claim 29 under §103 as being unpatentable over *Minevski* in view of *Pickford* or *Ogle* and further in view of *Rosenberg*. Applicant submits that the cited references do not provide a *prima faciè* case of obviousness for rejecting such claims.

Claim 29 is dependent upon independent claim 24. As noted above, *Minevski* in view of *Pickford* or *Ogle* does not teach or suggest all recitations of independent claim 24. Nothing in *Rosenberg* provides the missing recitations of independent claim 24.

Therefore, Applicant requests that the Examiner withdraw the §103 rejection of dependent claim 29, since it is submitted that independent claim 24 is allowable. Dependent claim 29 must be allowable, since such dependent claim 29 carries all the limitations of the allowable independent claim 24 to which it refers.

IV. Claims 13-15, 17, 19-21, 24, 25, 27-29, and 31 comply with the enablement requirement.

The Examiner has rejected the claims as failing to comply with the enablement requirement, under § 112. The crux of this rejection is that the claims, by not specifically setting forth the required process parameters, have failed to enable the production of the specified

surface layer. The requirement is surely that the description is required to enable any person skilled in the art to make and use the invention.

The description clearly teaches how to perform the process, and indeed explains what is occurring during the various stages. For example, page 5 lines 3-12 teach that:

The cleaned implant is then immersed in a stirred 12% (weight) solution of phosphoric acid, and is anodised for 2 hours at a maximum voltage of 100 V and a maximum current of 10 mA/cm², so as to form a surface coating of titanium oxide and phosphate. Within a couple of minutes a dense dielectric layer is formed on the surface, and the current then adopts a stable low value for the rest of the anodising period. The surface forms a hard surface layer which can have different coloured appearances due to optical interference effects

The process is further described on page 6 lines 7-15:

Referring to figure 2, where anodising is performed at a high voltage such as 100 V for 2 hours, as mentioned above the current initially falls to a low value, and then remains steady. The surface forms a hard anodised oxide layer 34 typically of thickness about 0.14 µm, but in which there are pits 36 typically of diameter about 5 µm and depth about 0.4 µm which are filled with titanium oxide as a result of hydrolysis from localised titanium dissolution.

Various ways of adjusting the silver capacity (i.e. the ion exchange capacity) are described at page 7 lines 31-36 and page 8 lines 8-11:

The silver capacity can be adjusted in three ways. It may be changed by changing the number of pits, and this can be either by changing the voltage, or by changing the concentration of pitting agents (such as chloride or fluoride ions) which are present as impurities in the phosphate electrolyte . . . Alternatively the pits might

be grown to larger depth and diameters; this may be achieved by carrying out the anodising for a longer period of time.

And the overall process is also discussed at page 8 lines 16-22:

By anodising at a higher voltage the thickness of the hard oxide layer can be increased, for example being about 0.7 μm at 500 V. Once this layer has been formed, as indicated by the decrease in the current, the voltage might be changed. During this second stage the pits are formed, and gradually grow in size, and this may be carried out at a lower voltage.

This describes how to perform the process. The person skilled in the art would have no difficulty in performing the process as described, and indeed, by virtue of the teachings of the specification, in modifying the number and size of the pits by adjusting the three parameters: the voltage, the duration of the anodising process, and the composition of the electrolyte.

V. Provisional Double Patenting

The Examiner has rejected claims 24, 25, 27-29 and 31 on the ground of "nonstatutory obviousness-type double patenting" over claims 1-11 of *the '028 application* in view of *Cooper* or *Minevski* (as described above). Upon an indication claims 13 and 24 are otherwise allowable, Applicant will consider whether a terminal disclaimer is an appropriate response to this rejection.

VI. Conclusion

Applicant respectfully requests reconsideration, allowance of the pending claims and a timely Notice of Allowance be issued in this case. If the Examiner feels that a telephone conference would expedite the resolution of this case, the Examiner is respectfully requested to contact the undersigned.

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Response to Office Action
Dated March 2, 2011

In the course of the foregoing discussions, Applicant may have at times referred to claim limitations in shorthand fashion or may have focused on a particular claim element. This discussion should not be interpreted to mean that the other limitations can be ignored or dismissed. The claims must be viewed as a whole, and each limitation of the claims must be considered when determining the patentability of the claims. Moreover, it should be understood that there may be other distinctions between the claims and the prior art that have yet to be raised but which may be raised in the future.

Respectfully submitted,

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